



The latest developments from U.S. FDA drugs and biologics Advisory Committee meetings.

# Today's Headline: Allergenic Product Reclassification Plans

April 7, 2005

Meeting Begin Time: 8:36 a.m. | End Time: 1:36 p.m.

## IN THIS ISSUE

[Allergenic Products Advisory Committee \[23064\]](#) Meeting

[AdComm Profiles and AdComm Voting](#) [43662]

**Subject:** The FDA's proposed strategy for the reclassification of Category IIIA allergenic products and an update of the FDA Critical Path Initiative.

**Announced in the Federal Register**

[March 8, 2005](#) [49071]  
(Volume 70, Number 44)

## Decision/Voting

There was no formal vote at this meeting of the [Allergenic Products Advisory Committee](#) [23064]. The committee discussed FDA's strategy concerning the 1985 recommended reclassification of Category IIIA allergenic products in an attempt to finish a classification project begun in 1972. There was a general opinion among the advisory committee that FDA's current plan of researching each of the 1200 remaining products for final reclassification and the elimination of the Category IIIA designation was good but a complicated process. The committee urged FDA to err on the side of too much research on a product and suggested an expansion of the search methods that will be used to collect the data. Finally, it was suggested that FDA highly publicize the reclassification process to notify healthcare providers of the possibility that some of these allergenic products may no longer be available and to encourage the submission of usage data on these products to facilitate their reclassification.

## Background Information

The [Allergenic Products Advisory Committee](#) [23064] convened to discuss the best method of implementation of the 1985 proposed rule based on the allergenic products reclassification panel's recommendations to reclassify all Category IIIA allergenic products as Category I or II. The committee also heard an update on FDA's Critical Path Initiative at this meeting.

## Reclassification of Class IIIA Allergenic Products

On February 13, 1973, FDA issued procedures for the review by independent advisory panels of the safety, effectiveness, and labeling of biological products licensed before July 1, 1972. This process was ultimately codified as 21 CFR 601.25 on November 20, 1973. FDA assigned the biological product review to one of the following groups:

- bacterial vaccines and bacterial antigens with "no US standard of potency,"
- bacterial vaccines and toxoids with standards of potency,
- viral vaccines and rickettsial vaccines,
- allergenic extracts,
- skin test antigens, and
- blood and blood derivatives.

Expert advisory panels were charged with preparing a report to the Commissioner of Food and Drugs which was to evaluate the safety and effectiveness of the biological products for which a license had been issued, review the labeling, and identify the biological products that are safe, effective, and not misbranded. Each advisory panel report was also to include recommendations classifying the products reviewed into one of three categories:

- Category I: safe; effective; and not misbranded
- Category II: unsafe; ineffective; or misbranded
- Category III: data insufficient for classification
  - IIIA: thought to have favorable risk-benefit ratio; remain on the market pending completion of testing
  - IIIB: thought to have unfavorable risk-benefit ratio; removal from the market pending completion of testing

Under the proposed order, FDA would revoke the licenses of those products designated into Category II and Category IIIB. More than 1500 substances were reviewed and categorized during the tenure of the board, 1974-1979. All the products were classified (most were classified as Category IIIA drugs as the panels felt there was insufficient safety and efficacy studies) and recommendations were made concerning, among other things, a continuation of studies of Category IIIA products.

In 1982 FDA codified in 21 CFR 601.26 the formation of reclassification panels to reclassify all IIIA products as Category I or II and these panels met from November 1982 until June 1983 and issued their recommendations. These recommendations were not implemented.

FDA now feels that these recommendations should be implemented and the committee was asked how the best way this should be done. As there currently exists 20 more years of data involving these allergenic products, in addition to *enhanced* data from the previous years dating back to 1972 which could be seen as “new” data, FDA suggested that all this available data be examined before implementing the reclassification panel’s recommendations. This includes searches for newly published data (i.e., PubMed, adverse events databases, etc.), reexamining the reclassification criteria of the 1982-1983 panel, and make final decisions on all 1200 products.

In January 2004, FDA issued a final rule and final order concerning the implementation of the efficacy panel recommendations ([Outdated: Federal Register: Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review - 21 CFR Parts 201 and 610 \(Final rule and final order\), 05-Jan-2004](#) [42220]) but withdrew the final rule almost a year later ([Federal Register: Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review - 21 CFR Parts 201 and 610; Withdrawal \(Final rule and final order; withdrawal\), 29-Dec-2004](#) [47959]) because the US District Court for the District of Columbia vacated the final rule and remanded to FDA for reconsideration.

### Critical Path Initiative Update

On March 16, 2004, FDA released [Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products](#) [43381], a white paper that addressed the recent slowdown in innovative medical therapies submitted to FDA for approval. The agency then established a [public docket](#) [44073] to obtain input on activities that could reduce existing hurdles in medical product design and development in an effort to reduce the cost of this development and increase predictability.

FDA is concerned about the lack of translation of recent advances in biomedical science to safer, more affordable, and more effective medical products. On October 7, 2004, FDA held a workshop to more adequately explain this initiative to those involved in the medical product design field. This workshop, [From Concept to Consumer: CBER Working with Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies](#) [46356] introduced each office within the FDA Center for Biologics

Evaluation and Research (CBER), noting their needs and abilities, in an effort to provide a public forum for input and discussion concerning opportunities for the enhancement of scientific knowledge and tools.

Other IDRAC resources concerning the Critical Path:

- [Impact Report: Decline in Drug Approvals is Driving Industry, FDA to Enhance Efficiency: Senior Executives Discuss Portfolio Management, "Critical Path" Initiative, January/February 2005](#) [49244]
- [Federal Register: Solicitation of Comments on Stimulating Innovation in Medical Technologies \(Notice\), 24-May-2004](#) [46502]

*To access IDRAC documents click on the hyperlinks within the AdComm Bulletin or use the IDRAC numbers noted in [brackets].*

- *Previous issues of the AdComm Bulletin are available in the US Module of IDRAC.*
  - *Search keyword: AdComm Bulletin*

#### Additional IDRAC Resources Briefing Information

- [Agenda](#) and Questions [49542]
- [Briefing Information](#) [49543]
- Slides - Handouts
- Transcript
- [Roster](#) [49544]
- Minutes

#### Future AdComm Bulletin and FDA Workshop Bulletin Coverage Schedule\*

Click here for: [AdComm Bulletin and FDA Workshop Bulletin Schedule Updates](#) [23827]

##### April

April 13, 2005: [FDA Workshop Bulletin](#) [39149]—  
Intravenous Immune Globulin in the 21st Century\*\*

##### May

May 3, 2005: [Advisory Committee for Pharmaceutical Science](#) [43591] (Day 1 of 2)

May 4, 2005: [Advisory Committee for Pharmaceutical Science](#) [43591] (Day 2 of 2)

May 5, 2005: [Oncologic Drugs Advisory Committee](#) [48605]

May 19, 2005: [Antiviral Drugs Advisory Committee](#) [48607]

##### June

June 6, 2005: [Pulmonary-Allergy Drugs Advisory Committee](#) [23061]

*\*Subject to change pending the FDA schedule.*

*\*\*FDA Workshop Bulletins are added directly to IDRAC's US-Module and availability is announced in the weekly IDRAC newsletter.*

**Don't forget, you will receive the Bulletin hours after an FDA Advisory Committee Meeting ends. There's simply no faster and easier way to stay informed.**

#### **AdComm Bulletin**

Executive Editor

[Jane S. Ricciuti, RPh, MS](#)

Senior Editor

[Regina M. Ballinger, RN](#)

Associate Editor

[Walter E. Chalkley](#)

Questions about the AdComm Bulletin? Send them to:  
[idracs-info@thomson.com](mailto:idracs-info@thomson.com)

Copyright ©2005 The Thomson Corporation

[Thomson Scientific](#)

All Rights Reserved.

Copying, reproduction, retransmission, or redistribution, including by framing or similar means of any material contained in the *AdComm Bulletin* in whole or in part or in any medium or form is prohibited without express permission.

Thomson Scientific

3501 Market Street, Philadelphia, PA 19104 USA

14 Great Queen Street, London WC2B 5DF UK

Palaceside Bldg. 5F, 1-1-1 Hitotsubashi, Chiyoda-ku, Tokyo 100-0003 Japan